administering to an animal at risk of such infection an effective amount of the vaccine of claim 1.

30. (New) The method of claim 29 wherein said animal is a human being.

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31. (New) A method of protecting an animal against pneumococcal infection by administering to an animal at risk of such infection an effective amount of the vaccine of claim 4.

32. (New) The method of claim 31 wherein said animal is a human being.

REMARKS

Claims 1-4 and 16 are pending in the case and have been rejected.

Drawings

Corrected drawings are required. Applicant requests that submission of such drawings be delayed until such time as allowable subject matter has been found.

Objections to the Specification

The specification has been objected to on grounds that Figure 3 actually encompasses Figures 3A and 3B. In response, Applicants have amended the specification to delete the phrase "Figure 3" wherever it occurs and to insert in its place

the phrase "Figures 3A and 3B."

The specification was also objected to for failure to insert the correct address for the American Type Culture Collection at page 34, lines 21-22, of the application. The correct address has been inserted by the present amendment.

In view of these amendments, Applicants believe that the asserted objections have been overcome and should be withdrawn.

Rejection under 37 U.S.C. §112

Claims 1-4, 16 were rejected under section 112, paragraph 1, as not being fully enabled by the specification. It was contended that these claims lack support for any and all variations in protein structure as having the requisite properties of a vaccine.

In response, Applicants have amended claim 1 to recite a vaccine at least 95% percent identical to SEQ ID NO: 6 and further requiring that the polypeptide induce production of antibodies when administered to a mouse. Support for this limitation is found especially at page 18, lines 22-25, of the application. Claims 2 and 3 have been cancelled. Claim 4 was not amended but depends from claim 1 and now recites the added limitation. Claim 4 is thus directed to a vaccine comprising the polypeptide of SEQ ID NO: 6, which is supported in the specification, especially at Figure 1.

Applicant believes that a vaccine containing a polypeptide comprising a sequence at least 95% identical to SEQ ID NO: 6 is supported in the specification at Figures 1, 3 and 4A. Figure 1 shows the ability of Sp128 (SEQ ID NO: 6) to protect mice against infection by a heterologous pneumococcal strain. Figure 3 shows that antisera against Sp130 reacted with pneumococcal surface proteins of a range of different strains all

containing a protein that incorporates Sp128 (SEQ ID NO: 6) and Sp130 (SEQ ID NO: 8). Figure 4A shows reactivity of patient sera with Sp128 (SEQ ID NO: 6). In other experiments, sera from 17 patients with pneumococcal infections were tested with Sp128 and 10 of 23 sera bound to Sp128 (see example 4 at page 36, lines 18-23). This variation in reactivity is believed to justify a vaccine containing a polypeptide sequence having at least 95% identity to Sp128 (SEQ ID NO: 6).

Claim 16 was likewise rejected under section 112, paragraph 1, as not being enabled by the specification because of its recitation of an "organism of the genus pneumococcus." This claim has been cancelled.

Claims 1-4 and 16 were also rejected under section 112, paragraph 2, as being indefinite.

Claim 1 has been amended to remove the recitation of immunogenic fragments and now covers a vaccine containing a polypeptide with at least 95% identity to SEQ ID NO: 6, whether this is a fragment of some polypeptide or not. This claim is believed to be definite based on the support cited for the amendment of this claim since the variability of sera reacting with the polypeptide contained in this vaccine and the detailed description of how to test the polypeptide with these sera is disclosed in Examples 1, 3 and 4 of the application.

Claim 16 was rejected as indefinite for use of the term "said polypeptide" in reference to a polypeptide recited earlier in the claim and because of dependence on claims 1-4, which do not use the term "*S. pneumoniae* polypeptides." The claim has been cancelled.

Claims 2-4 were rejected for indefiniteness on the same ground as claim 1. Claims 2 and 3 have been cancelled. Further, because claim 1 no longer recites fragments, claim 4 is no longer indefinite either.

New claims 29 to 32 are directed to methods of using the vaccines of claims 1 and 4 and should be allowable if claims 1 and 4 are allowable. These claims are supported in the application in the figures and in example 4 (pages 35-37).

New claims 23-28 are directed to an isolated polypeptide and methods of use and should be allowable because these4 are the polypeptides utilized in the vaccines of claim 1 and 4. This is supported in the specification by the results of Figure 1 and is believed to meet the requirements of section 112, paragraphs 1 and 2. These claims are also supported in the application at page 10, lines 18-20

Rejection under 37 U.S.C. §102

Claims 1-3 were also rejected under section 102(a) as anticipated by Bethe et al.

In response, Applicants note that the provisional priority case (60/138,453, filed 10 June 1999) fully discloses SEQ ID NO: 6 and herewith submit a copy of a downloaded document from the NCBI website. The EST provided in the Office Action indicated that it was submitted on 10 February 1999. However, the sequence revision history provided for this accession number (AF127143) shows that it was first seen at NCBI on 11 August 1999 (see attached Exhibit A). Applicants' claimed priority date is for the provisional application, Serial No. 60/138,453, filed 10 June 1999, which is prior to the August 11 date. Because this sequence was first seen at NCBI on August 11 date it would not constitute public knowledge prior to that date but at most only secret knowledge within the research group that made the submission.

It is well established law that the knowledge required by 37 U.S.C. 102(a) is public knowledge (see, generally, Chisum, 3.05[3]). The Examiner is also invited to review the following case law: In re Schlittler and Uffer, 110 USPQ 304 (CCPA 1956) ("the mere

placing of a manuscript in the hands of a publisher does not necessarily make it available to the public" (at page 308, ¶11) and concluding that the description in a manuscript submitted for publication does not constitute knowledge (at page 308, ¶14); Ex parte Osmond, Smith and Waite, 191 USPQ 334, at 337 (¶2) (Pat. Off. Bd. App. 1973) concluding that the knowledge contemplated by section 102(a) is required to be public knowledge; Rosemount, Inc. v. Beckman Instruments, Inc., 218 USPQ 881, at 896, ¶11 (C.D. Cal. 1983, aff'd 221 USPQ 1 (Fed. Cir. 1984) stating that "the knowledge or use by others required by Section 102(a) is public knowledge of a complete and operative device."; and Johnson and Johnson v. W.L. Gore & Assocs., 195 USPQ 487, at 492 (at footnote 6) (D. Del. 1977) holding that "The knowledge or use by others required by §102(a) is public knowledge of a complete and operative device."

Likewise, the deposit cannot meet the requirement that it was "described in a printed publication in this or a foreign country before the invention thereof by the applicant for a patent" because the public would not have had access to it prior to the August 11 date.

In addition, although the sequence was submitted on 10 February 1999, it fails to meet the requirement of 35 U.S.C. 102(a) that it be "known or used by others in this country" because, as noted from the printout contained in Exhibit B (which also recites the August 11, 1999, date), the research group making the submission was located in the Medical Microbiology Dept, University of Dusseldorf, in Germany. Thus, at the time of submission, there is no evidence that the sequence was not known or used by others in this country and was not available at NCBI until 11 August 1999, several months after Applicants 10 June 1999 priority date. (see, for example, Trend Products Co. v. Metro Indus., 10 USPQ 2d 1531, at 1538, ¶10 (C.D. Cal. 1989), holding that the invention being known or used by others outside of the U.S. does not bar a U.S. patent from issuing; also see: City of Milwaukee v. Activated Sludge, 21 USPQ 69 (7th Cir. 1934) holding that domestic knowledge of an invention reduced to practice abroad does not constitute anticipation).